



## **British Columbia's H1N1 Pandemic Influenza Response Plan (2009)**

# **Pandemic H1N1 Immunization Programs**

*November 9, 2009*

# PANDEMIC H1N1 INFLUENZA IMMUNIZATION

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The adjuvanted pandemic H1N1 (pH1N1) Arepanrix™ H1N1 vaccine was authorized by Health Canada on October 21<sup>st</sup> and delivery of this immunization program started in BC the week of October 26, 2009.

All British Columbians are eligible to be immunized; however, in the early weeks of the program the adjuvanted vaccine is available in limited quantities and it will be necessary to sequence priority groups for receipt.

Sequencing plans are as follows:

## Week of October 26:

- 1) those under 65 with high-risk medical conditions
- 2) women in the second half of pregnancy, any pregnant women with high-risk medical conditions, and pregnant women in the first half of pregnancy with informed consent.
- 3) residents of remote communities where access to timely health care services is very limited.

## Week of November 2:

- 5) children aged 6 months to under 5 years of age
- 6) household contacts younger than 65 years old of babies under 6 months old and of immunocompromised people
- 7) health care workers, including office-based physicians and staff, on a priority basis at their workplace with those delivering critical care and front-line services as a first priority.

## Week of November 9:

- 8) Health care workers (as above)
- 9) Women in the first half of pregnancy (using unadjuvanted vaccine)

Thereafter the vaccine program will be expanded based on vaccine supply and future prioritization decisions. For the sequencing rationale, see the Public Health Agency of Canada [Guidance document](#).

During the week of November 9<sup>th</sup>, an unadjuvanted H1N1 vaccine will be made available in BC under an Interim Order of the federal minister of health. This vaccine is indicated for use in pregnancy and priority should be given to women in the first half of pregnancy as there are no systematically collected data on use of adjuvanted influenza vaccines. Family doctors providing obstetrical care, obstetricians, and midwives should contact their local health unit to order for these patients.

Adjuvanted vaccine can be ordered by providers from the local health unit in the same manner as seasonal influenza vaccine. These inactivated split virus influenza vaccines are made by GlaxoSmithKline (GSK). The manufacture of both vaccines is based on the same process used for seasonal influenza vaccine, which includes eggs; therefore **anaphylaxis to eggs is a contraindication** to receipt of either vaccine. Both vaccines are given by the **intramuscular** route, as is seasonal influenza vaccine. A given recipient should receive only one of these vaccines, and not both.

## VACCINE DETAILS

The two pH1N1 vaccines contain the A/California/7/2009 (H1N1)v-like antigen, and are:

### 1. **Arepanrix, the adjuvanted pH1N1 vaccine**

- This vaccine requires mixing by withdrawal of all the adjuvant, a milky white substance in the smaller of the two vials, and injecting it into the larger vial containing the antigen, which is clear.
- The resulting whitish vaccine will be ten 0.5 ml doses or twenty 0.25 ml doses

- **After mixing**, record the time and date of mixing onto the vaccine vial; **this vaccine must be used within 24 hours** as stability cannot be assured beyond that time.
- Also record on the vial the lot number of the mixed product, which is located on the bubble wrap label or the outer shoebox
- Children 6 months to 9 years old should receive two 0.25 ml doses given at least 21 days apart. This recommendation may be revised to one dose in view of emerging information. Updates will be provided as research becomes available.
- Those aged 10 and older should receive one 0.5 ml dose.

2. **Influenza pH1N1 2009 Monovalent vaccine (without adjuvant)** will be available in November for pregnancy indications.

- This vaccine is formulated in the same way as Fluviral®, the seasonal trivalent vaccine from GSK.
- The early November supply will be in 5-ml vials and will contain “Clinical Formulation” on the label. The mid to late November supply will be in 10 dose vials; record the date of entry on the vial and **do not use for more than 28 days**.
- A single 0.5 ml dose should be given to pregnant women. The “Clinical Formulation” should be used preferentially in the first half of pregnancy as supplies will not be adequate to cover more than pregnancy indications.

## SPECIAL CONSIDERATIONS

### **Co-administration with seasonal flu and pneumococcal vaccines:**

The pH1N1 vaccines may be **co-administered with seasonal influenza** vaccine to people eligible for seasonal influenza vaccine, as well as with pneumococcal vaccines. The adjuvanted pH1N1 vaccine should be given in a separate limb from that used for other vaccines. Those who do not wish to receive both pandemic and seasonal influenza vaccines at the same visit should be advised to receive pH1N1 vaccine first, as seasonal strains are not circulating in BC at this time but pandemic virus activity is high.

### **Pregnancy**

Only adjuvanted vaccine will be available in BC until the week of November 9<sup>th</sup>. Adjuvanted vaccine should be offered to pregnant women at 20+ weeks’ gestation. Pregnant women under 20 weeks gestation who have chronic medical conditions should discuss the risks and benefits of receiving adjuvanted vaccine or waiting until unadjuvanted vaccine is available with their health care provider. Once unadjuvanted vaccine is available it should be preferentially offered throughout pregnancy. If your supplies of the unadjuvanted vaccine are limited, use it preferentially in women <20 weeks gestation. There are no known risks of using adjuvanted vaccine in pregnancy, and the recommendation to use unadjuvanted vaccine preferentially is precautionary due to insufficient data.

### **Children under 6 months of age**

Neither vaccine should be given to children younger than 6 months of age.

### **Adverse events**

Both vaccines are associated with local site reactions such as pain, redness and swelling at the injection site. Pain at the injection site is very common with the adjuvanted vaccine.

There may also be tender swelling in the regional lymph nodes such as axillary or supraclavicular following deltoid injection. Systemic adverse events such as myalgia, headache and fatigue are also reported among recipients, and are more common following the adjuvanted vaccine. These events should resolve in a few days. Do not report such events as Adverse Events Following Immunization.

Do report severe or unusual events, and events requiring medical attention or hospitalization that you believe to be associated with receipt of these vaccines. Report to your local health unit/ medical health officer using the [British Columbia Adverse Events Following Immunization Reporting Form](#)

Early reports from BC health providers and those in other Canadian jurisdictions indicate that serious allergic events i.e. anaphylaxis may occur at a rate of around 1 per 100,000.

### **Additional reference materials**

Please review the Instructional Slide Set for Immunizers and the accompanying Questions and Answers posted on the PHO website and at the [Health Professionals section](#) of [www.immunizebc.ca](http://www.immunizebc.ca) for Immunizers prior to administering these vaccines as these documents contain additional information about recommended recipients, injection equipment, the adjuvant and the safety profile of these vaccines. These instructional materials will be updated on an ongoing basis. Please check back frequently for updates.

### **Product leaflets**

The product leaflet was not distributed with early shipments of the adjuvanted vaccines. A BCCDC product leaflet has been enclosed with subsequent shipments of both the adjuvanted and unadjuvanted vaccines.

GSK materials are available online at: <http://www.gsk.ca/english/html/our-products/vaccines-canada.html>.